

Long-term effect of altering the source and amount of dietary carbohydrate in type 2 diabetes

Submission date

24/02/2006

Recruitment status

No longer recruiting

Registration date

24/02/2006

Overall study status

Completed

Last Edited

05/04/2012

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00223574

Protocol serial number

MCT-44205

Study information

Scientific Title

Comparison of the long-term effect of reducing the glycaemic index versus reducing the amount of dietary carbohydrate in type 2 diabetes: a randomised controlled trial

Acronym

CCD (Canadian trial of dietary Carbohydrates in Diabetes)

Study objectives

To compare the effects, in subjects with diabetes treated by diet alone, of reducing glycaemic load by replacing high glycaemic index (GI) starchy foods with low GI starchy foods (i.e. reducing diet GI) versus low carbohydrate foods rich in monounsaturated fat (i.e. reducing the amount of dietary carbohydrate).

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Toronto Research Ethics Board, St Michael's Hospital gave approval on the 19th December 2001

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus

Interventions

Group 1 - high carbohydrate, high glycaemic index starchy foods (control); duration 12 months

Group 2 - high carbohydrate, low glycaemic index starchy foods; duration 12 months

Group 3 - low carbohydrate foods, high in monounsaturated fat; duration 12 months

Trial details received: 12 Sept 2005

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Glycated haemoglobin (A1c) measured at -2 and 0 weeks and at 3, 6, 9 and 12 months after randomisation (measure at 12 months is done twice; at 50 and 52 weeks).

Key secondary outcome(s)

1. Fasting plasma: total, low density lipoprotein (LDL) and high density lipoprotein (HDL) cholesterol, triglycerides, Apolipoprotein A (Apo A), Apolipoprotein B (Apo B), C-reactive protein (CRP), free fatty acids (FFA), glucose, insulin, acetate, propionate, butyrate all measured at baseline and at 1, 3, 6, 9 and 12 months after randomisation
2. Oral glucose tolerance: area under curve (AUC) for glucose and insulin, two-hour glucose, insulinogenic index measured at baseline and at 3, 6 and 12 months after randomisation. Eight-hour metabolic profile for glucose, insulin, triglycerides and FFA measured at baseline and 12 months after randomisation.
3. Body weight, waist circumference, blood pressure measured at 2 - 4 week intervals throughout the trial
4. Quality of life and activity index measured at baseline and 12 months after randomisation
5. Intakes of carbohydrate, fiber, starch, sugars, total fat, saturated fat, polyunsaturated fatty acids (PUFA) and monounsaturated fatty acids (MUFA), protein, glycaemic index and glycaemic load measured using a three-day food record two times at baseline and 1, 3, 6, 9 and 12 months after randomisation

Completion date

31/01/2004

Eligibility

Key inclusion criteria

1. Male or non-pregnant females
2. Aged 40 - 70 years old
3. Body mass index less than 40 kg/m²
4. HbA1c less than or equal to 8.5%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Absence of diabetes
2. Age less than 40 years or greater than 70 years
3. Pregnancy or lactation
4. Body mass index greater than or equal to 40 kg/m²
5. Use of any hypoglycaemic or anti-hyperglycaemic drug
6. HbA1c greater than 8.5%
7. Major cardiovascular event (stroke, myocardial infraction) or surgery within six months
8. Serum triglycerides greater than 10 mmol/l
9. Presence of other major debilitating disorder such as liver disease, renal failure, cancer
10. Presence of gastrointestinal disorder or use of a drug which is likely to alter gastrointestinal motility or nutrient absorption

- 11. Substance abuse
- 12. Simultaneous participation in another clinical trial

Date of first enrolment

01/04/2001

Date of final enrolment

31/01/2004

Locations

Countries of recruitment

Canada

Study participating centre

Department of Nutritional Sciences

Toronto

Canada

M5S 3E2

Sponsor information

Organisation

University of Toronto (Canada)

ROR

<https://ror.org/03dbr7087>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-44205)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2008		Yes	No
Results article	disposition index results	01/09/2008		Yes	No
Results article	results	01/03/2013		Yes	No